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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

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1649

DATE MAILED:

09/28/98

ART UNIT

PAPER NUMBER

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/963,096	Applicant(s) Zuo-Yu Zhao et al.
Examiner Gary Benzion, Ph.D.	Group Art Unit 1649

Responsive to communication(s) filed on 27 Jul 1998

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 62-73 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 62-73 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Status of the Application

Effective February 7, 1998, the Group and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1649.

Claims 62-73 are pending.

Applicant's IDS of pages 1-4 is acknowledged.

The drawing submitted with this application are objected to under 37 CFR 1.85 informal but are considered acceptable for examination purposes. See attached PTO form 948.

Detailed Action

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 62-73 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention. This is a new matter rejection.

The specification, while being enabling for *Agrobacterium*-mediated transformation of *Zea mays* in which the transformation step is carried out in the absence of an antibiotic that mediated against the growth of the transforming bacteria, does not reasonably provide enablement or written description for the claimed step in which said antibiotic is applied during transformation or sequentially after transformation, in the absence of a time interval to allow the bacteria to transfer plasmid DNA into the target cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Beginning at page 20 of the disclosure, under the section devoted to co-cultivation, at page 22 it is stated:

Following the co-cultivation step, the embryos are optionally transferred to a second plate of solid medium containing an antibiotic capable of inhibiting the growth of *Agrobacterium*.

The specification does not teach a step of co-cultivation in which the antibiotic capable of inhibiting the growth of *Agrobacterium* is applied during transformation or sequentially after transformation. As such the specification does not support by enablement or written description the invention as claimed.

Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 62-73 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Grimsley et al. (US Patent # 5,569,597).

Grimsley et al. disclose *Zea mays* cells and plants which have been prepared by a process in which the cell of the immature-embryos have been contacted with *Agrobacterium* comprising at least one gene, co-cultivated, and grown in the presence of a selective agent against bacterial growth and that for selection of plants cells which express said gene. These authors state:

Suitable plant material comprises both whole plants as well as parts of plants. Parts of plants are for example also protoplasts, cell culture cells, cells in plant tissue, pollen, pollen robes, egg-cells, embryo-sacs, zygotes or embryos in different stages of development as well as whole plants.

In a further embodiment of the present invention, the inoculation of the microorganism-containing transforming inoculation solution is carried out on the immature developing embryo after pollination and fertilisation of the ovules by the sperm nucleus, but preferably before the seed coat has developed. Immature embryos are either inoculated immediately after isolation or are first germinated up to 3 days in the dark before being involved into the inoculation procedure.

In using immature embryos, apart from the inoculation techniques already mentioned it is also possible to use a process in which the embryo is first of all, in preparation, removed from the mother plant and then brought into contact with the transfer microorganism in a suitable culture medium [IK Vasil, 1984; Pareddy D et al, 1987]. A further preferred method of application includes co-cultivating of shoots of plant seedlings germinated from immature embryos, with the *Agrobacterium* containing solution, said shoots being obtainable by germinating embryos on a suitable agar medium and isolating the developing shoots from the seedlings by cutting just below the coleoptilar node, where the shoot meristem is located. In particular, the shoots are dipped into the *Agrobacterium* suspension and then preferably subjected to vacuum infiltration. The infiltrated shoots are cultured on the agar plates of a suitable medium, but preferably a MS medium. . . .

EXAMPLE 13

Inoculation of Immature Embryos

The apical meristem or the shoot apex of immature embryos as small as 1 mm is punctured with a Microlance 26G.sup.3 /8 0.45.times.10 fine needle, and the smaller embryos are punctured with a drawn out .mu.lass microcapillary. Immediately after puncturing, 2 to 4 .mu.l of an overnight *Agrobacterium* culture containing the MSV construct according to Example 5 is applied. Bacteria are obtained with a liter of 10.sup.9 cells per milliliter, washed, and resuspended in 10 mM MgSO₄ to the same concentration. Successive subcultivations are done up to 3 days for each germination series. After every subcultivation step, the presence of correct pLE1 sequences is tested by restriction analysis after plasmid isolation by an alkaline lysis procedure (Sambrook et al., 1989). Inoculated immature embryos are incubated with the apical side on the MS medium for 24 hr in the dark, then flipped over and incubated for another day on the same medium under 16-hr light, 10,000 lux, 25.degree. C. followed by an 8-hr dark, 20.degree. C. regime. Embryos

are then transferred onto 0.8% agar solidified MS medium containing 3% sucrose, 1 mg/liter thiamine-HCl, 500 .mu.g/ml cefotaxim (Hoechst, Frankfurt, Germany), and 500 .mu.g/ml carbenicillin against *Agrobacterium* growth. After 1 week, immature planlets are transferred into Magenta boxes containing MS medium solidified with 0.8% agar and containing 2% sucrose and 1 mg/liter thaimine-HCl. ...

Thus the cells and plant produced by regeneration therefrom are identical to applicants claimed composition, they are derived from the same source and possess the same characteristics, that is a gene transferred from *Agrobacterium* to the plant cell and plant produced therefrom. Grimsley et al. do not teach the use of N6 medium in the place of MS medium for growth or inoculation, however, the claimed invention is set forth in product-by-process limitations in which a product, in the absence of evidence to the contrary, is considered met by the product found in the prior arts in the absence of evidence that the process steps impart any characteristics to the composition. While it is noted that the disclosure teach the benefits of using N6 over MS during certain steps in the process, there is no evidence that the product produced comprises characteristics not found in the prior art. Accordingly identity of the claimed invention with that in the prior art is assumed. It is applicants burden to prove that the prior art composition does not anticipate or at least make obvious the invention as claimed. See, *In re Best*, 562 F.2d 1252, 195 USPQ 430 *In re Brown*, 459 F.2d 531, 173 USPQ 685 (CCPA 1972) and *In re Marosi* 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983).

Claims 62-73 rejected under 35 U.S.C § 103 as being unpatentable over Grimsley et al. in view of Carswell et al. .

Grimsley et al. disclose *Zea mays* cells and plants which have been prepared by a process in which the cell of the immature-embryos have been contacted with *Agrobacterium* comprising at least one gene, ,co-cultivated, and grown in the presence of a selective agent against bacterial growth and that for selection of plants cells which express said gene. Grimsley et al do not teach the use of N6 medium as applied to the process of *Agrobacterium* transformation of *Zea mays* cells. Carswell et al. (US Patent # 5,595,733) disclose the use of different media to regenerate maize and present evidence that the use of either MS or N6 do not affect the composition of cells or plants produced by those cells. They state:

The callus is removed from the cultured immature embryos and placed on maintenance medium. Any maintenance medium capable of sustaining callus proliferation may be used. Some suitable examples include but are not limited to those based on MS medium, N6 medium, B5 medium or KM medium, with appropriate concentrations of sugars and plant growth regulators. The material is subcultured to fresh maintenance medium at appropriate intervals, for example, every 1 to 120 days, preferably 3 to 21 days, and most preferably 5 to 14 days. Initiation and

maintenance may be carried out in the light or dark, preferably in the dark. The temperature may be between 0.degree. C. and 50.degree. C., preferably between 20.degree. C. and 32.degree. C., most preferably between 25.degree. C. and 28.degree. C.

Accordingly the prior art disclose that the claimed composition, *Zea mays* cells, transformed cells and plants therefrom, produced by any process, have the same characteristics as that claimed herein. Thus, the claimed invention as a whole was clearly *prima facie* obvious in view of the references, in the absence of a preponderance of the evidence to the contrary.

Summary

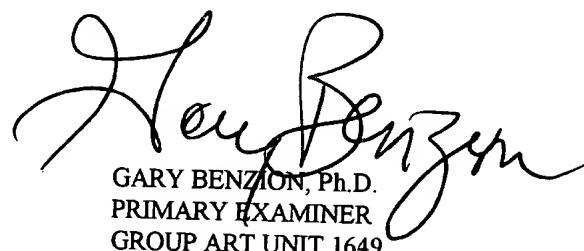
No claim is allowed.

Inquiries

Any inquiry concerning this or earlier communication from the examiner should be directed to Gary Benzion, Ph.D. whose telephone number is (703) 308-1119. The examiner can normally be reached on Monday-Friday from 7:03 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas W. Robinson can be reached on (703)-308-2897. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Benzion
09/27/98



GARY BENZION, Ph.D.
PRIMARY EXAMINER
GROUP ART UNIT 1649